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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,174	06/14/2005	Bernd Haber	02/085 NUT	5165

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/539,174	HABER ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The terminal disclaimer filed on 10/06/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/538,903 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1-24 are presented for examination on the merits.

The preliminary amendment to the claims received on 06/14/2006 has been acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marco et al. (US 5,856,313), Breivik et al. (US 5,502,077), and McKenney (Lipid Management) for the reasons set forth in the previous Office Action and restated below.

Marco et al. beneficially teach a carob product which contains insoluble carob fiber (see e.g. col 1, lines 5-10). Marco et al. further beneficially teach that the carob product has a hypocholesterol-aemiant effect, which can counteract the effects of modern cholesterol-rich diets (see e.g. col 1, lines 34-39). Marco et al. also disclose that in rats fed a high cholesterol diet, the increase in cholesterol in a test group which

was fed the carob fiber product was significantly lower than those fed another type of fiber (see e.g. all of column 5). Therefore, the carob product beneficially taught by Marco et al. would intrinsically have the effect of reducing cholesterol. Marco et al. do not beneficially teach that the product additionally contains at least one n-3 fatty acid or at least one cholesterol-reducing active compound.

Breivik et al. beneficially teach a fatty acid composition which comprises omega-3-fatty acids (see e.g. abstract). Breivik et al. further beneficially teach that the composition contains omega-3 fatty acids, specifically, a combination of 5,8,11,14,17-eicosapentaenoic acid and 4,7,10,13,16,19-docosahexaenoic acid (see e.g. claim 1). It is further disclosed by Breivik et al. that the composition is useful for treatment or prophylaxis of multiple risk factors known for cardiovascular disease, including hypertriglyceridemia (see e.g. col 10, lines 34-39) and that it has been shown that the composition lowers total serum cholesterol significantly (see e.g. col 9, lines19-24).

McKenney beneficially teaches a number of treatments for hypercholesterolemia, including several cholesterol-reducing active compounds. McKenney beneficially teaches that statins, bile acid resins (bile acid sequestrants), niacin (a nicotinic acid derivative), and fibrates are useful in reducing cholesterol (see e.g. 301-304). McKenney further beneficially teaches that fiber from vegetables and dietary adjuncts such as fiber and stanol/sterol esters can lower LDL cholesterol (see e.g. p. 300), which would read on the instantly claimed phytosterols, plant sterols and cholesterol-reducing plant extracts.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the insoluble fiber containing carob product beneficially taught by Marco et al. with the n-3 fatty acid composition beneficially taught by Breivik et al and any of the cholesterol reducing active compounds beneficially taught by McKenney and well known in the art to obtain a cholesterol lowering agent as instantly claimed. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit- i.e. reducing cholesterol -since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose (as well as to use the combination for that purpose). The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The adjustment of particular conventional working conditions (e.g. the particular result-effective combination of one or more of the instantly claimed agents or the particular

form of the agent) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding new claims 21-24 please note that the judicious selection of particular result effective amounts of individual components is considered routine optimization which is well within the purview of the skilled artisan. Furthermore, the particular source of the n-3- fatty acids instantly claimed would not render the composition unique over the prior art because the structure of the n-3 fatty acid would necessarily be the same if it were indeed an n-3 fatty acid.

Applicants argue that the instantly claimed agent comprising water insoluble carob fiber and at least one n-3 fatty acid provides synergistic reduction in cholesterol levels which is greater than the sum of the effects when the carob fiber or n-3 fatty acid are administered alone. However, such a synergistic result has not been demonstrated. Applicants further argue that the references (US '313, US '077, and Lipid Management) do not teach the synergistic effect instantly claimed. However, Marco et al. (US '313) beneficially teach that insoluble carob fiber is useful for reducing cholesterol and Breivik

et al. (US '077) beneficially teach that n-3 fatty acids are useful in reducing cholesterol. McKenney (Lipid Management) beneficially teaches that statins, bile acid resins (bile acid sequestrants), niacin (a nicotinic acid derivative), and fibrates are useful in reducing cholesterol. McKenney further beneficially teaches that fiber from vegetables and dietary adjuncts such as fiber and stanol/sterol esters can lower LDL cholesterol. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine insoluble carob fiber, n-3 fatty acids and at least one of statins, bile acid sequestrants, nicotinic acid derivatives, fibrates, and plant stanols for the purpose of reducing cholesterol.

Applicants further argue that the carob fiber beneficially taught by Marco et al. (US 5,856,313) is not disclosed as having a particular length. However, applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed invention.

Applicants argue Breivik et al. teach that DHA (a fatty acid) has not been shown to have an effect on hypertension. However, applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed invention. Applicants also argue that Breivik et al. do not teach administration of 4,7,10,13,16,19 –docasahexaenoic acid. However, as previously stated, Breivik et al. do teach administration of 4,7,10,13,16,19 –docasahexaenoic acid (see e.g. claim 1). While Breivik et al. do not expressly teach administration of 4,7,10,13,16,19 –docasahexaenoic acid alone, Breivik et al. do teach that the fatty acid compositions disclosed in US '077 (including 4,7,10,13,16,19 –docasahexaenoic acid) are valuable in

treating hypertriglyceridemia (see e.g. col 10, lines 34-40). Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide 4,7,10,13,16,19 –docasahexaenoic acid for the purpose of reducing cholesterol as, instantly claimed.

Applicants also argue that McKenney does not teach the synergistic combination of the carob fiber, n-3 fatty acid and cholesterol-reducing active agent as instantly claimed. McKenney does, however teach that fiber from vegetables (which would include carob fiber), omega-3 fatty acids (n-3 fatty acids) and dietary adjuncts including stanol esters and other cholesterol-reducing active agents, including statins, bile acid sequestrants, nicotinic acid derivatives, and fibrates are effective in reducing cholesterol (see e.g. page 300, col 2- page 304, col 1). Applicants further argue that McKenney teaches away from the instantly claimed invention by teaching the combination of drugs as providing advantageous results. McKenney teaches drugs and other agents (n-3 fatty acids and fiber), as instantly claimed, which are well known in the medical art to reduce cholesterol. Combining them or using them individually to reduce cholesterol would have been obvious to one of ordinary skill in the art at the time the claimed invention was made, especially in view of the beneficial teachings of Marco et al. and Breivik et al.

Provided the combined teachings of Marco et al., Breivik et al., and McKenney, one of ordinary skill in the art would have been motivated to provide a composition which comprises the elements instantly claimed for the same purpose (reducing cholesterol). As previously stated no invention resides in combining old ingredients of

known properties where the results obtained thereby are no more than the additive effect of the ingredients. Thus, the rejection is deemed proper and is maintained.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTOPHER R. TATE
PRIMARY EXAMINER